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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1655	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/509,261	PLOCH ET AL.	
	Examiner	Art Unit	
	Amy L. Clark	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-16,18-25,29,30 and 34-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-16,18-25,29,30 and 34-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on 9 April 2007 with the cancellation of Claims 17, 26-28 and 31-33, and newly added Claims 31-41.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 14-16, 18-25, 29, 30 and 34-41 are under examination.

Claim Objections

Newly amended claims 14, 15, and 36-41 are objected to because of the following informalities: please correct claim 14 to read "(St. John's wort)~~-~~, *Gingko biloba* (gingko)~~-~~, *Crocus Sativus* (saffron)~~,~~ *Panax ginseng* (ginseng) and pharmaceutically acceptable salts thereof" in lines 3-5. Please note that the line between the end parentheses in the example above is a deletion mark, since there is an unnecessary space between the end parenthesis and the comma. Please make the same corrections to claim 40 (See lines 3 and 4). Also insert a space between "*Panax* ginseng" and "(ginseng)" in line 4 and insert a comma between "thereof" and "wherein" in line 4. Please correct claim 15 to read "according to claim 14~~,~~ wherein said at least one medicament" in lines 1 and 2. Please make this correction (insertion of a comma before "wherein") in line 2 of claim 36, in line 1 of claim 37, in line 1 of claim 38, line 2 of claim 39 and in line 1 of claim 41. Please remove the extra space in claim 24, line 2 between "," and "wherein" and in line 3 between "of" and "*Gingko biloba*", in claim 37,

line 2 between "is" and "selected", and between "of" and "haloperidol" and in line 4 between "," and "clozapine", in claim 38 between "wherein" and "a" in line 1, and in claim 40, line 3, between "(St. John's wort)" and "," and between "(gingko)" and ",". Appropriate correction is required. Newly applied as necessitated by amendment.

Claims 14, 19, 24, 25 and 40 objected to because of the following informalities: "gingko" is misspelled. The correct spelling is ginkgo. Please note that this correction should be applied to the Latin name (*Ginkgo biloba*) and to the common name. Appropriate correction is required. Newly applied as necessitated by amendment.

Claim 16 is objected to because of the following informalities: please insert in a ratio of between "is" and "between" in line 5 and line 6. Appropriate correction is required. Newly applied as necessitated by amendment.

Newly amended claims 18-21, 23, 24, 29, 30, 39 and 40 are objected to because of the following informalities: claims 18, 29, 30 are objected to because "herpericins" (in line 3 of all of the claims) is misspelled. The correct spelling is hypericins. Claims 18-21, 23, 24, 29, 30, 39 and 40 all contain ranges wherein the ranges are written with the following formula: 0.01-2% (in the case of claim 18). Please replace "-" with to in all cases (see lines 3 and 4 of claim 18, lines 3 and 4 of claim 19, line 5 of claim 20, line 4 of claim 21, line 4 of claim 23, line 2 of claim 24, lines 3 and 4 of claim 29, lines 3 and 4 of claim 30, lines 2 and 3 of claim 39 and line 5 of claim 40). Please also italicize "inter alia" in line 2 of claim 21 and correct "saponines" to read saponins in line 3 of claim 21. Please note that Applicant has misspelled "degredation" (line 4 of claim 20). The correct spelling is degradation. Please further correct claim 20 by amending lines 3 and

4 to read, "*α*-, and *β*-pinene, ~~1, 8 cineol~~ 1,8-cineol, crocin, and picocrocin, and wherein the saffron extract optionally further comprises safranal (a degradation product of [please insert what safranal is a degradation product of]) ~~as well as optionally the degredation product thereof safranal~~" (please also see the rejection under 112 2nd paragraph below since it is unclear as to what Applicant is intending to claim. The Examiner is making this correction based upon how the Examiner believes that Applicant is intending to describe this part of the claim. The entire claim must be amended to comply with the 112 2nd paragraph rejection below, so this amendment proposed by the Examiner of claim 20 is not complete). Appropriate correction is required. Newly applied as necessitated by amendment.

Claims 24 and 25 are objected to because of the following informalities: "gingko biloba, Crocis sativus and Panax ginseng" in lines 3 and 4 of claim 24, and "gingko biloba" and "Panax ginseng" in lines 3 and 4 of claim 25 should be corrected to read *Ginkgo biloba*, *Crocis sativus* and *Panax ginseng* in claim 24, and *Ginkgo biloba* and *Panax ginseng* in claim 25. Appropriate correction is required. Newly applied as necessitated by amendment.

Newly amended claim 30 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Newly applied as necessitated by amendment.

Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form. Newly amended claim 16, from which claim 30 depends, is written as, "The pharmaceutical composition

according to claim 15, wherein the extract used is an alcohol or alcohol-aqueous extract containing primary, secondary or tertiary alcohols having 1 to 5 carbons, preferably methanol and ethanol, wherein the alcohol/water content of the composition is between 100/0 to 30/70 by volume, preferably 80/20 to 50/50 by volume" and is clearly drawn to a composition, whereas claim 30 is written as, "The use according to claim 16, wherein the St. Johns' wort extract comprises he following components by weight percent: 0.10-2% herpercins, 0.01-30% hyperforins, 2-35% flavonoids, preferably 0.10 to 0.40% hypercins and 1-6% hyerforins", and is clearly drawn to some sort of method.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-16, 18-25, 29, 30 and 34-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Newly applied as necessitated by amendment.

Enablement is considered in view of the *Wands* factors (MPEP 2164.O1(A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art predictability of the art and the amount of experimentation necessary. All of the Wands factors have been

considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the Invention: The claims are drawn to "A pharmaceutical composition comprising: at least one medicament selected from the group consisting of *Hypericum perforatum* (St. John's wort), *Gingko biloba* (gingko), *Crocus Sativus* (saffron), *Panax ginseng* (ginseng) and pharmaceutical acceptable salts thereof; and a pharmaceutically acceptable carrier" as claim 14, "A pharmaceutical composition in the form of a suspension, a dragee, an effervescent tablet, an effervescent granulate, a chewable tablet or a suppository containing St. John's wort, *Gingko biloba*, saffron and/or *Panax ginseng* in addition to, as further components, a psychotherapeutic drug for the simultaneous, separate or graduated treatment of schizophrenia as claim 25, "A method for treating schizophrenia, comprising administering a therapeutically effective amount of the pharmaceutical composition of claim 14" as claim 34, "A method for treating schizophrenia wherein a therapeutically effective amount of the pharmaceutical composition of claim 23 is administered up to 3 times per day" as claim 38, and "A pharmaceutical composition comprising: at least one medicament selected from the group consisting of *Hypericum perforatum* (St. John's wort), *Gingko biloba* (gingko), *Crocus Sativus* (saffron), *Panax ginseng* (ginseng) and pharmaceutical acceptable salts thereof wherein said pharmaceutical composition contains 50 mg – 1000 mg of said at least one medicament; and a pharmaceutically acceptable carrier" as claim 40.

Breadth of the Claims: The claims are broad in that a therapeutically effective amount of a composition comprising: at least one medicament selected from the group

consisting of *Hypericum perforatum* (St. John's wort), *Gingko biloba* (gingko), *Crocus Sativus* (saffron), and *Panax ginseng* (ginseng) may be administered to treat schizophrenia in a patient. The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims.

Guidance of the Specification and Existence of Working Examples: The specification describes a method for measuring the ketamine-antagonistic effect of hypericum extract as a parameter that shows a possible effectiveness of St John's wart (Jarsin® 750 mg, Lichtwer Pharma AG, Berlin, Germany) on the negative symptoms of patients with chronic schizophrenia (See pages 9-11).

The specification envisions that a composition comprising: at least one medicament selected from the group consisting of *Hypericum perforatum* (St. John's wort), *Gingko biloba* (gingko), *Crocus Sativus* (saffron), and *Panax ginseng* (ginseng) will have utility in humans in treating schizophrenia.

However, no working examples are provided with regard to a method for treating schizophrenia. Furthermore, no working examples are provided that demonstrate the efficacy of a composition comprising: at least one medicament selected from the group consisting of *Hypericum perforatum* (St. John's wort), *Gingko biloba* (gingko), *Crocus Sativus* (saffron), and *Panax ginseng* (ginseng) in the treatment of schizophrenia.

Predictability and State of the Art: The state of the art at the time the invention was made was unpredictable and underdeveloped. For example, Akhondzadeh (U, 'The 5-HT hypothesis of schizophrenia'. Idrugs, Vo. 4, no. 3 (Mar 2001), pp 295-300. PubMed Abstract) teaches that early theories of schizophrenia implicated disturbed

serotonin (5-HT) neurotransmission, but these were largely overshadowed by the dopamine theory of schizophrenia, which became established after the introduction of chlorpromazine, however, the importance of 5-HT in CNS function is once again being recognized. Akhondzadeh further teaches that the ability of antipsychotic drugs to diminish positive symptoms has been correlated with their ability to block dopamine D(2) receptors, although negative symptoms are not as effectively treated by typical neuroleptics and that there is increasing interest in the correlation between negative symptoms of schizophrenia and 5-HT(2) receptors. Akhondzadeh further teaches that the rationale for these studies is the hypothesis that abnormal neurotransmission at 5-HT(2) receptors may be involved in the pathophysiology of schizophrenia. Therefore, the exact cause of schizophrenia is not currently known and how to treat negative symptoms is not currently understood completely. Lal et al. (V, 'St. John's wort and schizophrenia.' Canadian Medical Association Journal, Vol. 163, no. 3 (August 8, 2000), pp. 262-263) teaches that 2 patients with schizophrenia experienced psychotic relapse that was temporally associated with the consumption of St. Johns' wort (See page 263).

Thus, while the claim-designated method may be useful for providing such an effect, Applicant does not disclose a method comprising the administration of compositions comprising: at least one medicament selected from the group consisting of *Hypericum perforatum* (St. John's wort), *Gingko biloba* (gingko), *Crocus Sativus* (saffron), *Panax ginseng* (ginseng) and pharmaceutical acceptable salts thereof for treating schizophrenia. The Office further notes that while the specification discloses that the claim-designated methods and claim designated compositions will have utility in

humans in treating schizophrenia, nowhere in the specification or in the limitations does Applicant direct the claimed subject matter to the administration of a composition comprising: at least one medicament selected from the group consisting of *Hypericum perforatum* (St. John's wort), *Gingko biloba* (gingko), *Crocus Sativus* (saffron), *Panax ginseng* (ginseng) and pharmaceutical acceptable salts thereof to any subject.

It should be noted that at the time of filing of the present application, the art of medicine did not recognize the administration of a composition comprising: at least one medicament selected from the group consisting of *Hypericum perforatum* (St. John's wort), *Gingko biloba* (gingko), *Crocus Sativus* (saffron), *Panax ginseng* (ginseng) and pharmaceutical acceptable salts thereof for the treatment of schizophrenia comprising the step of administering a composition comprising: at least one medicament selected from the group consisting of *Hypericum perforatum* (St. John's wort), *Gingko biloba* (gingko), *Crocus Sativus* (saffron), *Panax ginseng* (ginseng) and pharmaceutical acceptable salts thereof on its own, wherein said compositions pharmaceutical composition comprising: at least one medicament selected from the group consisting of *Hypericum perforatum* (St. John's wort), *Gingko biloba* (gingko), *Crocus Sativus* (saffron), *Panax ginseng* (ginseng) and pharmaceutical acceptable salts thereof treat schizophrenia in humans.

Amount of Experimentation Necessary: The quantity of experimentation necessary to carry out the claimed invention is high, as the skilled artisan could not rely on the prior art or instant specification to teach how to make and use any compositions comprising: at least one medicament selected from the group consisting of *Hypericum*

perforatum (St. John's wort), *Gingko biloba* (gingko), *Crocus Sativus* (saffron), *Panax ginseng* (ginseng) and pharmaceutical acceptable salts thereof in the treatment of schizophrenia in humans. In order to carry out the claimed invention, one of ordinary skill in the art would have to identify compositions comprising: at least one medicament selected from the group consisting of *Hypericum perforatum* (St. John's wort), *Gingko biloba* (gingko), *Crocus Sativus* (saffron), *Panax ginseng* (ginseng) and pharmaceutical acceptable salts thereof that can be administered in a therapeutically effective dose with an acceptable level of side-effects.

In view of the breadth of the claims and the lack of guidance provided by the specification as well as the unpredictability of the art, the skilled artisan would have required an undue amount of experimentation to make and/or use the claimed invention. Therefore, Claims 14-16, 18-25, 29, 30 and 34-41 are not considered to be fully enabled by the instant specification.

Claim 21 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a "written description" rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, & 1 "Written Description" Requirement, Federal Register, Vol. 66,

No. 4, pages 1099-1111, Friday January 5, 2001. Newly applied as necessitated by amendment.

Vas-Cath Inc. V. Mahurka, 19 USPQ2d 1111, states that applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the "written description" inquiry, is "*whatever is now claimed*" (See page 1117).

A review of the language of the claim indicates that this claim is drawn to "The pharmaceutical composition according to claim 15, wherein the ginseng root extract comprises the components by weight, *inter alia*, triterpene saponins (ginsengosides/ginsenoids), sesquiterpenes and polyacetylenes, particularly preferred in the following concentrations: 3-9% ginsenoids".

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In *Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that, while applicants are not required to disclose every species encompassed by a genus, the description of the genus is achieved by the recitation of a representative number of species falling within the scope of the claimed genus. At section B (1), the court states

"An adequate written description of a DNA ... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention". Hence, an adequate written description of the ingredients requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984). Accordingly, describing "The pharmaceutical composition according to claim 15, wherein the ginseng root extract comprises the components by weight, *inter alia*, triterpene saponins (ginsengosides/ginsenoids), sesquiterpenes and polyacetylenes, particularly preferred in the following concentrations: 3-9% ginsenoids", in the absence of knowledge as to what the material consists of or the source of the material is not a description of the material. However, other than the composition described by Applicant in the originally presented specification, wherein Applicant simply discloses, "ginseng root extracts contain, *inter alia*, triterpene saponines (ginsenosides/ginsenoids), sesquiterpenes and polyacetylenes, particularly preferred in the following concentrations: 3-9% ginsenoids" (See paragraph 0051 in the specification of the PreGrant publication), Applicant fails to adequately describe as to what Applicant defines or considers as "ginsenoids". For example, nowhere in the present specification does Applicant render a definition of the term "ginsenoids" nor does Applicant cite an example of this term thereof.

One of skill in the art would not recognize from the disclosure that the applicant was in possession of the genus of what constitutes "ginsenoids". The specification does not clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed (see *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15, 16, 18-24, 29, 30 and 39-41 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. All rejections newly applied as necessitated by amendment.

The metes and bounds of Claim 15 are rendered uncertain by the phrase "The pharmaceutical composition according to claim 14, wherein said at least one medicament is in a form of a plant, plant parts, a dried plant or plant parts, an extract, an extract fraction, or salts thereof" because it is unclear as to what Applicant is claiming. It appears that Applicant is claiming that the medicament may be in the form of a whole plant, or parts of a plant, or of a dried plant or of dried plant parts or of an extract or of a fraction of an extract, but there are several parts of this claim that are completely ambiguous. First of all, if Applicant is claiming the medicament is the whole plant, how does Applicant intend for the whole plant to be mixed with a pharmaceutically

acceptable carrier. Is Applicant saying that the plant part is a tincture? The same is true of the plants parts, dried plant and dried plant parts. Secondly, it is unclear as to what Applicant means by salts of a plant, plant part, dried plant, dried plant parts, extract, or an extract fraction. Does Applicant mean that the extract or extract fraction are specific compounds and that these specific compounds or their salts may be used? Salts of a plant part, plant, dried plant, extract of a plant, etcetera does not make any sense whatsoever. Finally, what does Applicant mean by "extract" and "extract fraction" (See line 3)? Is Applicant claiming a specific compound, a solvent extract or something else? Furthermore, what is an "extract fraction"? Is Applicant claiming that the extract has been separated into fractions and a fraction may be used or is Applicant claiming that a small amount of the extract may be used (a fraction of an extract)? The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

The metes and bounds of Claim 16 are rendered uncertain by the phrase "The pharmaceutical composition according to claim 15, wherein the extract used is an alcohol, or alcohol-aqueous extract containing primary, secondary, or tertiary alcohols having 1 to 5 carbon, preferably methanol and ethanol, wherein the alcohol/water content of the composition is between 100/0 to 30/70 by volume, preferably 80/20 to 50/50 by volume" because it is unclear if Applicant is claiming that the extract is obtained by alcohol extraction or if the extract itself contains alcohol. Furthermore, it is unclear if Applicant is claiming that the composition inherently contains alcohol in the ration provided by Applicant or if Applicant is intending to claim a ratio of each solvent

used to perform an extraction of a particular plant in the ranges claimed by Applicant. Finally, is Applicant claiming a ratio in lines 5 and 6? If so, then Applicant should indicate that the amounts listed are meant to be ratios and Applicant should clean up the language to indicate that the ratio starts at 100/0 and ends at 30/70, unless Applicant is intending to claim that the ratio does not incorporate each end of the range of ratios. If this is the case, then Applicant should indicate this in the claim. The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

Claims 18-21, 29, 30 and 40 recites the limitation "the St. John's wort extract" in line 2 of claim 18, in line 2 of claim 29 and in line 1 of claim 30, "the gingko extract" in line 2 of claim 19, "the saffron extract" in line 2 of claim 20, "the ginseng extract" in line 2 of claim 21, and "said at least one medicament" in claim 49. There is insufficient antecedent basis for these limitations in the claim. Furthermore, with regards to "said at least one medicament" in claim 40, it is unclear if Applicant means that only one of the medicaments in claim 40 is in present in an amount of 50 mg to 1000 mg or if each medicament is present in this amount of if the total amount of all medicaments present in this amount. It is unclear as to what Applicant means by "wherein the saffron extract comprises the following components in weight percent α-, β-pinene, 1, 8 cineol, crocin, picocrocin as well as optionally the degradation product thereof safranal, particularly preferred in the following concentrations by weight" in lines 2-5 of claim 21 because it is unclear as to what degradation product safranal is. Is safranal the degradation product of the extract of saffron, or is safranal a degradation product of one of the compounds

found in saffron extract. If this is the case, then Applicant needs to identify which compound is the precursor to safranol. Also, the wording of this claim must be amended because the phrase "the following components in weight percent" is unclear since Applicant does not list any amounts following each compound. Applicant eventually discloses which ranges of amounts of each component are preferable but the way the claim is currently worded is confusing and ambiguous. Finally, it is unclear as to what Applicant means by "The pharmaceutical composition according to claim 15, wherein the ginseng root extract comprises the components by weight, *inter alia*, triterpene saponins (ginsengosides/ginsenoids), sesquiterpenes and polyacetylenes, particularly preferred in the following concentrations: 3-9% ginsenoids" in clain 21because it is unclear as to what Applicant means by "wherein the ginseng root extract comprises the components by weight, *inter alia*, triterpene saponins (ginsengosides/ginsenoids), sesquiterpenes and polyacetylenes" since Applicant does not provide any amounts of each component by weight and it is unclear as to what Applicant means by "ginsenoids" (please see 112 1st paragraph written description rejection above). The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

The metes and bounds of Claims 23, 24, 39 and 40 are rendered uncertain by the phrase "The pharmaceutical composition according to claim 15, wherein said pharmaceutical composition contains 300 to 2700 mg, preferably 750 –1500 mg of St. John's wort" as claim 23, "The pharmaceutical composition according to claim 15, wherein said pharmaceutical composition contains 50 mg-1000 mg of at least one

extract" as claim 24, "A method for treating schizophrenia comprising administering the pharmaceutical composition of claim 24, wherein the daily dose of the extracts if 50 mg –1000 mg" as claim 39 and "A pharmaceutical composition comprising: at least one medicament selected from the group consisting of *Hypericum perforatum* (St. John's wort), *Gingko biloba* (gingko), *Crocus Sativus* (saffron), *Panax ginseng* (ginseng) and pharmaceutical acceptable salts thereof, wherein said pharmaceutical composition contains 50 mg – 100 mg of said at least one medicament; and a pharmaceutically acceptable carrier" as claim 40 because the amounts of the ingredients are not set forth in terms of either 'by weight" or "by volume" amount of the total composition. The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14-16, 18, 22-24, 29, 30, 40 and 41 are rejected under 35 U.S.C. 102(a) as being anticipated by Bombardelli et al. (A, US PreGrant Publication: 2001/0000326 A1). Newly applied as necessitated by amendment.

Bombardelli teaches an extract of *Hypericum perforatum* obtained by extracting with 98% methanol comprising 25% hyperforin, 1.2% hypericin and 1.2% dimeric diflavones (See page 3, Example 3, paragraph 0040) and that the extract may be included in formulations for oral use, such as tablets, capsule and solutions (See page 3, paragraph 0036 and page 4, Claim 13). Bombardelli further teaches that the dosage of extract in the formulations is preferably 300 mg per dose, daily (See page 3, paragraph 0036). Bombardelli further teaches that a pharmaceutical composition comprising an extract of *Hypericum perforatum* contains a pharmaceutically acceptable excipient or carrier (See page 4, claim 17).

It is noted that the reference does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ

430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency and product-by-process claims.

Therefore, the reference anticipates the claimed subject matter.

Claims 14-16, 19, 21, 22, 24, 40 and 41 are rejected under 35 U.S.C. 102(a) as being anticipated by Petrini et al. (B, US PreGrant Publication: 2002/0015744 A1). Newly applied as necessitated by amendment.

Petrini teaches a dietary supplement or medication consisting essentially of a combination of ginseng and ginkgo extracts to improve memory (See abstract and page 2, paragraphs 0016-0020 and paragraph 0037), wherein the extracts may be obtained by a suitable solvent, such as water, ethanol, or mixtures thereof (See page 2, paragraph 0023), and wherein the supplement or medicament may be in the form of tablets, coated tablets, powders, solutions, suspension and in suspensions of water, ethanol or a mixture thereof (See page 2, paragraph 0021 and 0037), which reads on pharmaceutically acceptable carrier. Petrini further teaches that the composition may be administered in an amount of 100 mg *Panax ginseng* extract and 60 mg *Ginkgo biloba* extract (See page 2, paragraph 0030-0032). Petrini further teaches that the ginseng extract contains at least 4% ginsenosides and that the ginkgo extract contains 24% ginkgo flavone glycosides and 6% terpene lactones (See page 2, paragraphs 0034-0036).

It is noted that the reference does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition

does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency and product-by-process claims.

Therefore, the reference anticipates the claimed subject matter.

Claims 14-16, 19, 22, 40 and 41 are rejected under 35 U.S.C. 102(a) as being anticipated by Schwabe (C, US Patent Number: 5,322,688). Newly applied as necessitated by amendment.

Schwabe teaches an extract obtained from *Ginkgo biloba* leaves, wherein the *Ginkgo biloba* is extracted with ethanol or butan-2-ol to provide an extract containing 24.8 weight percent flavone glycosides, 3.2% ginkgolides (See column 4, lines 50-54), and 25.3% flavone glycosides and 3.4% ginkgolides (See column 5, lines 7-11).

Schwabe further teaches a solution for oral administration or a coated tablet comprising an extract of *Ginkgo biloba* further comprising a pharmaceutically acceptable carrier (See column 5, "Example 3" and "Example 4" and column 8, claim 12).

It is noted that the reference does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency and product-by-process claims.

Therefore, the reference anticipates the claimed subject matter.

Claims 14-16, 22, 24, 40 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Mori et al. (N, JP 11-080009 A, Translation provided herein). Newly applied as necessitated by amendment.

Mori teaches a medicine for brain function comprising saffron powder or an extract of saffron and ginkgo extract, wherein the daily dose of saffron is 3-300 mg and of ginkgo is 5-500 mg (See Abstract). Mori further teaches that the extract of saffron (*Crocus sativus*) and the extract of ginkgo may be obtained by extraction of each plant with alcohol or mixture of water and alcohol (See paragraphs 0010 and 0011) and that the medicine may be in the form of a tablet, capsule, powder, granulation, liquid, solution, etc. (See paragraph 0021) and that the capsules are coated in gelatin (See paragraph 0023), which reads on pharmaceutically acceptable carrier.

It is noted that the reference does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use,

new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency and product-by-process claims.

Therefore, the reference anticipates the claimed subject matter.

Claim 29 is rejected under 35 U.S.C. 102(b) as being anticipated by Zhang et al. (W, 'A Double-Blind, Placebo-Controlled Trial of Extract of *Ginkgo biloba* added to Haloperidol in Treatment-Resistant Patients with Schizophrenia. Journal of Clinical Psychiatry, vol. 62, No. 11 (November 2001), pp. 878-883). Newly applied as necessitated by amendment.

Zhang teaches a method for treating patients with schizophrenia comprising administering a fixed dose of 360 mg/day (9 tablets) of an extract of *Ginkgo biloba* plus haloperidol with three times daily dosing (See page 878 and page 879, "Study Design"). Zhang further teaches that the *Ginkgo biloba* extract comprises flavonal glycosides in an amount of 24% and terpene substances ginkgolides and bilobade in an amount of 6% (See page 879, "Study Design").

Therefore, the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 34-37 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. (W, 'A Double-Blind, Placebo-Controlled Trial of Extract of *Ginkgo biloba* added to Haloperidol in Treatment-Resistant Patients with Schizophrenia. Journal of Clinical Psychiatry, vol. 62, No. 11 (November 2001), pp. 878-883), in view of Petrini et al. (B, US PreGrant Publication: 2002/0015744 A1). Newly applied as necessitated by amendment.

The teachings of Zhang are set forth above and applied as before.

The teachings of Petrini are set forth above and applied as before.

The teachings of Zhang and Petrini are set forth above. Zhang does not

expressly teach a composition comprising an extract of *Ginkgo biloba* and a pharmaceutically acceptable carrier. However, at the time the invention was made, it would have been obvious to one of ordinary skill in the art and one would have been motivated and had a reasonable expectation of success to modify the method taught by Zhang to provide the instantly claimed invention because at the time the invention was made, a method for treating patients with schizophrenia comprising administering a fixed dose of 360 mg/day (9 tablets) of an extract of *Ginkgo biloba*, wherein the extract comprises flavonal glycosides in an amount of 24% and terpene substances ginkgolides and bilobade in an amount of 6%, and haloperidol with three times daily dosing was known, as clearly taught by Zhang, as was a that a composition comprising a combination of ginseng and ginkgo extracts, wherein the extracts may be obtained by a suitable solvent, such as water, ethanol, or mixtures thereof, wherein the supplement or medicament may be in the form of tablets, coated tablets, powders, solutions, suspension and in suspensions of water, ethanol or a mixture thereof, which reads on pharmaceutically acceptable carrier, that the composition may be administered in an amount of 100 mg *Panax ginseng* extract and 60 mg *Ginkgo biloba* extract, and that the ginseng extract contains at least 4% ginsenosides and that the ginkgo extract contains 24% ginkgo flavone glycosides and 6% terpene lactones.

Therefore, it would have been merely a matter of judicious selection to one of ordinary skill in the art at the time the invention was made to modify the referenced composition because it would have been well in the purview of one of ordinary skill in the art practicing the invention to add a pharmaceutically acceptable carrier to a

composition comprising an extract of *Ginkgo biloba* for oral administration in the form of a tablet, wherein the extract of *Ginkgo biloba* contains 24% ginkgo flavone glycosides and 6% terpene lactones. Thus, the claimed invention is no more than the routine optimization of a result effect variable.

* Applicant is advised that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources. Should you receive inquiries about the use of the Office's PAIR system, applicants may be referred to the Electronic Business Center (EBC) at http://www.uspto.gov/ebc/index.html or 1-866-217-9197.

Response to Arguments

Information Disclosure Statement

US patent: 4,892,882 and US patent: 4,571,407 have been considered by the Examiner.

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 30 provides for the use according to claim 16, wherein the St. Johns' wort

extract comprises he following components by weight percent: 0.10-2% hypercins, 0.01-30% hyperforins, 2-35% flavonoids, preferably 0.10 to 0.40% hypercins and 1-6% hyperforins, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 30 remains rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 101

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Newly amended claim 30 remains rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Applicant claims, "Use according to claim 16, wherein the St. Johns' wort extract comprises he following components by weight percent: 0.10-2% herpercins, 0.01-30% hyperforins, 2-35% flavonoids, preferably 0.10 to 0.40% hypercins and 1-6% hyerforins". It is unclear whether Applicant is claiming a method of using the

composition of claim 16 or if Applicant is claiming a method of making the composition of claim 16 since no active steps of how to use the claimed product are recited. The claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). Therefore, the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Newly amended claim 30 also remains rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102

Applicant's arguments, see "Applicant Arguments/Remarks Made in an Amendment", filed 9 April 2007, with respect to the rejection(s) of claim 25 under 35 U.S.C. 102(b) as being anticipated by Song (X*, Chinese Patent Abstract, CN 1171264 A) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new grounds of rejection is made under 35 U.S.C. 102(b) as being anticipated by Zhang et al. (W, 'A Double-Blind, Placebo-Controlled Trial of Extract of *Ginkgo biloba* added to Haloperidol in Treatment-

Resistant Patients with Schizophrenia. Journal of Clinical Psychiatry, vol. 62, No. 11 (November 2001), pp. 878-883).

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571) 272-1310. The examiner can normally be reached on 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amy L. Clark
AU 1655

Amy L. Clark
June 28, 2007

MICHELE FLOOD
PRIMARY EXAMINER